K033138

DEC - 2 2003

7. 510(k) SUMMARY AS REQUIRED UNDER 21 CFR 807.87(h)

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR:	ETEX Corporation 38 Sidney Street, 3rd Floor Cambridge, MA 02139 Phone: (617) 577-7270 Fax: (617) 577-7170
510(k) CONTACT:	Duke Lee, Ph.D. Chief Scientific Officer
TRADE NAME:	CaP_3™ Bone Substitute Material
COMMON NAME:	Bone Void Filler Bone Graft Material Bone Substitute Material
CLASSIFICATION:	Class II
CLASSIFICATION NAME:	21 CFR 888.3045 Resorbable Calcium Salt Bone Void Filler Device
PRODUCT CODE:	MQV
PREDICATE DEVICES:	α-BSM® Bone Substitute Material (K011048)

DEVICE DESCRIPTION:

CaP_3™ Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. It is intended for use in bone void filler applications in the spine, pelvis, and extremities. At the time of use, the CaP_3™ product material is combined with the mixing liquid (U.S.P. Sodium Chloride, 0.9%), and is mixed to form a paste. The paste can be administered to the treatment site by manual application, and be shaped in situ or into a desired form prior to implantation. After applying the paste to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order and has a similar chemical identity and crystalline structure to that of natural bone. CaP_3™ Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

INDICATIONS FOR USE:

CaP_3™ Bone Substitute Material is an implantable bone graft, that is a synthetic, calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CaP_3™ Bone Substitute Material is a bone graft substitute that resorbs and is replaced with bone during the healing process.

BASIS OF SUBSTANTIAL EQUIVALENCE:

CaP_3™ Bone Substitute Material is a synthetic bone graft substitute material substantially equivalent to α-BSM® Bone Substitute Material. Both materials are provided sterile and as single patient, single use kits and are identical in intended use (i.e., bone void filler indications). CaP_3™ Bone Substitute Material is also similar to α-BSM® Bone Substitute Material in material properties and in product performance characteristics. Differences between the CaP_3™ and α-BSM® products do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 2003

Duke Lee, Ph. D.
Chief Scientific Officer
ETEX Corporation
University Park at MIT
38 Sidney Street
Cambridge, MA 02139

Re: K033138
Trade Name: CaP3 Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 26, 2003
Received: September 30, 2003

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K033138

Device Name: CaP_3 Bone Substitute Material

Indications for Use:

CaP_3 Bone Substitute Material is an implantable bone graft, that is a synthetic, calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CaP_3 Bone Substitute Material is a bone graft substitute that resorbs and is replaced with bone during the healing process.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use

(Per 21 CFR 801.109)

for Mark N Melkerson

Division Sign-Off
Division of General, Restorative
and Neurological Devices

510(k) Number K033138

K033138 MNM